

**NUFLOR GOLD - florfenicol injection**  
Schering Corporation

Injectable Solution, An Antimicrobial  
300 mg/mL

**For subcutaneous use in beef and non-lactating dairy cattle only**

**Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal**

**PRODUCT  
INFORMATION**

**CAUTION**

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION**

NUFLOR GOLD™ is an injectable solution of the synthetic antibiotic florfenicol. Each milliliter of sterile NUFLOR GOLD™ contains 300 mg of florfenicol, 300 mg of 2-pyrrolidone, and triacetin qs.

**INDICATION**

NUFLOR GOLD™ is indicated for treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle.

**DOSAGE AND ADMINISTRATION**

NUFLOR GOLD™ should be administered once by subcutaneous injection at a dose rate of 40 mg florfenicol/kg body weight (6 mL/100 lb). Do not administer more than 15 mL at each site. The injection should be given only in the neck. Injection sites other than the neck have not been evaluated.

**NUFLOR GOLD™ Dosage Guide**

<b>ANIMAL WEIGHT (lb)</b>	<b>DOSAGE (mL)</b>
100	6.0
200	12.0
300	18.0
400	24.0
500	30.0
600	36.0
700	42.0
800	48.0
900	54.0
1000	60.0

**Recommended Injection Location:**



**CONTRAINDICATIONS**

Do not use in animals that have shown hypersensitivity to florfenicol.

**WARNINGS**

**NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.** This product contains materials that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothing. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Consult a physician if irritation persists. Accidental injection of this product may cause local irritation. Consult a physician immediately. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information.

For customer service, to report suspected adverse reactions, or to obtain a copy of the MSDS, call 1-800-211-3573.

**PRECAUTIONS**

Not for use in animals intended for breeding purposes. The effects of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy.

Subcutaneous injection in cattle can cause a transient local tissue reaction that may result in trim loss of edible tissue at slaughter.

## RESIDUE WARNINGS

Animals intended for human consumption must not be slaughtered within 44 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

## ADVERSE REACTIONS

Transient inappetence, diarrhea, decreased water consumption, and injection site swelling have been associated with the use of florfenicol in cattle. In addition, anaphylaxis and collapse have been reported post-approval with the use of another formulation of florfenicol in cattle.

## CLINICAL PHARMACOLOGY

The pharmacokinetic disposition of NUFLOR GOLD™ was evaluated in feeder calves following a single subcutaneous injection at a dose rate of 40 mg florfenicol/kg body weight. Administration of NUFLOR GOLD™ resulted in florfenicol plasma concentrations of 2 µg (mcg)/mL within two hours of injection.

Table 1. Pharmacokinetic Parameter Values for Florfenicol Following a Single Subcutaneous Injection of NUFLOR GOLD™ at a Dose Rate of 40 mg Florfenicol/kg Body Weight to Feeder Calves (n=24).

	<b>C<sub>max</sub></b> <b>(µg/mL)</b>	<b>T<sub>max</sub></b> <b>(hr)</b>	<b>AUC<sub>last</sub></b> <b>(µg*hr/mL)</b>	<b>T<sub>1/2</sub></b> <b>(hr)</b>
n	24	24	24	23*
Mean	5.93	5 <sup>†</sup>	150	37.7
% CV	38.3	2-12 <sup>†</sup>	20.9	27.3

C<sub>max</sub>: Maximum observed plasma concentration

T<sub>max</sub>: Time at which C<sub>max</sub> was observed

AUC<sub>last</sub>: Area under the plasma-concentration-time curve from time zero to the last quantifiable concentration that is equal to or greater than the limit of quantification of the validated analytical method

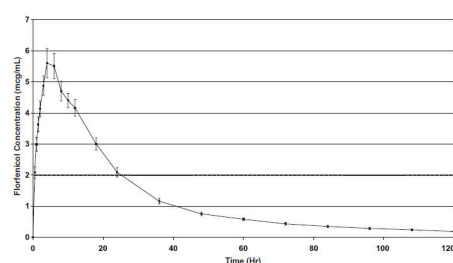
T<sub>1/2</sub>: Terminal elimination half-life

% CV: Percent coefficient of variance

\*T<sub>1/2</sub> value could not be accurately estimated for one calf

<sup>†</sup>T<sub>max</sub> is presented as the median value or range of observed values (minimum to maximum)

**Figure 1. Mean Florfenicol Plasma Concentration versus Time Following a Single Subcutaneous Injection of NUFLOR GOLD™ at a Dose Rate of 40 mg Florfenicol/kg Body Weight in Feeder Calves (Mean ± Standard Error of the Mean)**



## MICROBIOLOGY

Florfenicol is a synthetic, broad-spectrum antibiotic active against many Gram-negative and Gram-positive bacteria isolated from domestic animals. It acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Florfenicol is generally considered a bacteriostatic drug, but it exhibits bactericidal activity against certain bacterial species. *In vitro* studies demonstrate that florfenicol is active against the BRD pathogens *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis* and that florfenicol exhibits bactericidal activity against strains of *M. haemolytica* and *H. somni*.

The minimum inhibitory concentrations (MICs) of florfenicol were determined for BRD isolates obtained from calves enrolled in BRD field studies in the U.S. in 2006 using methods recommended by the Clinical and Laboratory Standards Institute (M31-A2). Isolates were obtained from pre-treatment nasal swabs from all calves enrolled at all four sites, post-treatment nasal swabs from treatment failures in the NUFLOR GOLD Injectable Solution and saline control treatment groups at three sites, and lung tissue from one calf that died in the saline control treatment group. The results are shown below in Table 2.

Table 2. Florfenicol MIC values \* of indicated pathogens isolated from cattle with naturally-occurring BRD

Indicated pathogens	Year of isolation	No. of isolates	MIC <sub>50</sub> <sup>†</sup> (µg/mL)	MIC <sub>90</sub> <sup>†</sup> (µg/mL)	MIC range (µg/mL)
<i>Mannheimia haemolytica</i>	2006	158	1.0	1.0	0.5 to 32
<i>Pasteurella multocida</i>	2006	103	0.5	0.5	≤ 0.125 to 16
<i>Histophilus somni</i>	2006	85	≤ 0.125	≤ 0.125	≤ 0.125 to 0.25

\*The correlation between *in vitro* susceptibility data and clinical effectiveness is unknown.

†The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

## ANIMAL SAFETY

A target animal safety study was conducted to evaluate the effects of NUFLOL GOLD™ when administered to feeder cattle by subcutaneous injection at 1X, 3X, or 5X the labeled dose for three consecutive days (3X the labeled duration). Decreased feed consumption (inappetence), decreased water consumption, and injection site swelling were observed in the 1X, 3X, and 5X groups. A separate injection site study conducted in cattle demonstrated that NUFLOL GOLD™ may induce a transient local reaction in the subcutaneous tissue and underlying muscle tissue.

## STORAGE INFORMATION

Store between 2°-30°C (36°-86°F). Use within 28 days of first use. Refrigeration is not required. The solution is light yellow to straw colored. Color does not affect potency.

## HOW SUPPLIED

NUFLOL GOLD™ is packaged in 100 mL (NDC 0061-5327-01), 250 mL (NDC 0061-5327-02), and 500 mL (NDC 0061-5327-03) glass sterile multiple-dose vials.

Made in Germany

Intervet Inc., Roseland, NJ 07068

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B-31331005 7/09

F-31331005

NADA 141-265, Approved by FDA.

## PRINCIPAL DISPLAY PANEL - 100 ML VIAL LABEL

**NuflorGOLD™**

(florfenicol)

**Injectable Solution, An Antimicrobial**

**For subcutaneous use in beef and non-lactating dairy cattle only**

**Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian

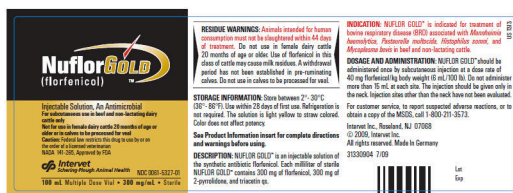
NADA 141-265, Approved by FDA

**Intervet**

**Schering-Plough Animal Health**

NDC 0061-5327-01

**100 mL Multiple Dose Vial • 300 mg/mL • Sterile**



## PRINCIPAL DISPLAY PANEL - 100 ML VIAL CARTON

**NuflorGOLD™**

(florfenicol)

**Injectable Solution,**

## An Antimicrobial

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian  
NADA 141-265, Approved by FDA  
NDC 0061-5327-01

**Intervet**

**Schering-Plough Animal Health**

**100 mL Multiple Dose Vial • 300 mg/mL • Sterile**



## PRINCIPAL DISPLAY PANEL - 250 ML VIAL LABEL

**NufloR GOLD™**

(florfenicol)

**Injectable Solution, An Antimicrobial**

**For subcutaneous use in beef and non-lactating dairy cattle only**

**Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian

NADA 141-265, Approved by FDA

**Intervet**

**Schering-Plough Animal Health**

NDC 0061-5327-02

**250 mL Multiple Dose Vial • 300 mg/mL • Sterile**



## PRINCIPAL DISPLAY PANEL - 500 ML VIAL LABEL

**NufloR GOLD™**

(florfenicol)

**Injectable Solution, An Antimicrobial**

**For subcutaneous use in beef and non-lactating dairy cattle only**


**Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian

NADA 141-265, Approved by FDA

**Intervet**

Schering-Plough Animal Health  
NDC 0061-5327-03  
500 mL Multiple Dose Vial • 300 mg/mL • Sterile



**NufloR GOLD**  
(florfenicol)

**Injectable Solution, An Antimicrobial**  
for intramuscular use in beef and veal finishing dairy cattle.

Beef calves to finish dairy cattle 28 months of age or older or calves to be processed for veal.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**MSD Vet. Div., Kenilworth, NJ 07033**

**Intervet**  
Schering-Plough Animal Health

**NDC 0061-5327-03**  
500 mL Multiple Dose Vial • 300 mg/mL • Sterile

**INDICATION:** NUFLOR GOLD<sup>®</sup> is indicated for treatment of bovine respiratory disease (BRD) caused by *Mycoplasma bovis*, *Mycoplasma agalactiae*, *Mycoplasma dispartus*, *Mycoplasma mycoides*, and *Mycoplasma fortuitum*.

**DOSE AND ADMINISTRATION:** NufloR GOLD<sup>®</sup> should be administered once by intramuscular injection at a dose rate of 6.6 mg (based on live weight) of 100% NUFLOR GOLD<sup>®</sup> solution every 12 to 24 hours. The solution should be given into the neck. Injection sites other than the neck have not been evaluated.

**CONTRAINDICATIONS:** NufloR GOLD<sup>®</sup> is contraindicated in calves less than 12 months of age.

**WARNINGS:** NufloR GOLD<sup>®</sup> is contraindicated in calves less than 12 months of age.

**PRECAUTIONS:** NufloR GOLD<sup>®</sup> is contraindicated in calves less than 12 months of age.

**ADVERSE REACTIONS:** NufloR GOLD<sup>®</sup> is contraindicated in calves less than 12 months of age.

**HOW SUPPLIED:** NufloR GOLD<sup>®</sup> is supplied in 500 mL multiple dose vials.

**US 1812 3.5**